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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/748,621

12/30/2003

Frank L. Neely

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EXAMINER

WEBB, WALTER E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/14/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/748,621	Applicant(s) NEELY ET AL.	
	Examiner WALTER E. WEBB	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-15,28 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 2,11 16-27, and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-15,28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

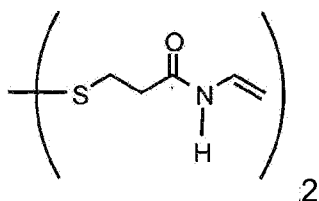
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|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/21/2008, 7/24/2007, 10/11/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 2, 11, 16-27, and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election of claims 1, 3-10, 12-15, and 28-29 in the reply filed on 1/31/2008 is acknowledged. Applicants have elected where the ligand monomer is:



They have also elected where the lens is made of senofilcon A. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it). Accordingly, the values recited by instant claims 4-7 are incomplete insofar as they do not specify the frame of reference used to measure them, e.g., 0.01 to about 1.5 weight percent.

In order to overcome this ground of rejection the examiner recommends inserting the parameters by which the weight is measured.

Based on the above reasoning, the instantly claimed percentage values in claims 4-7 are indefinite insofar as the total against which they are computed is not provided, e.g., "based on the weight of the lens".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

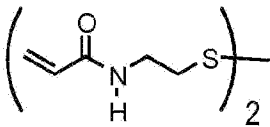
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-10, 12-15 and 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma et al., (US 5,213,801) in view of Nochumson, (US 4,542,200) and in further view of Vanderlaan et al., (US 5,998,498).

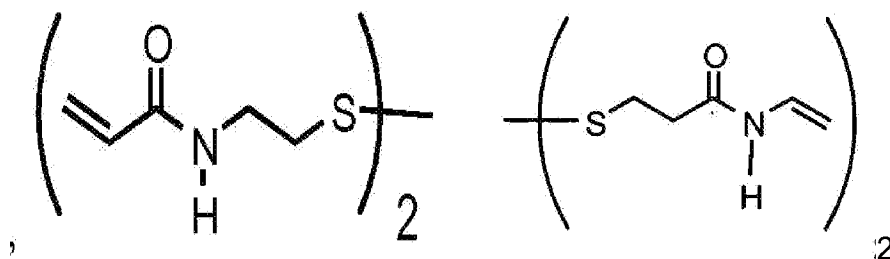
Sakuma et al. teach an antibacterial soft contact lens material comprising a hydrogel lens material and an antibacterial ceramic containing at least one metal, where the metal can be silver (Ag). (See abstract.) They teach that the amount of silver should be small, generally 10% or less by weight. (See col. 2, lines 63-67.)

Sakuma et al. differs from the instant claims insofar as it does not teach incorporation of the elected monomer or that the lens is senofilcon A.

Nochumson teaches a polyacrylamide film comprising polyacrylamide cross-linked with a polysaccharide resin. (See abstract and claim 1.) The reference teaches

the use of N,N'-bisacrylylcystamine, represented here , as a cross-linker in producing polyacrylamide gels. (See col. 1, lines 57-61.)

This monomer differs from the instant monomer in that the amide is reversed. See comparison below:



Prior art monomer

Instant monomer

Vanderlaan et al. teach that a hydrogel is a hydrated cross-linked polymeric system and is a preferred material for producing contact lenses. (See col. 1, lines 11-15.) They teach a silicone hydrogel comprising senofilcon A represented by structure I. (See col. 2, lines 24-43.) They teach that adding this monomer will increase oxygen permeability of the hydrogels and is soft enough to make soft contact lenses. (See col. 2, lines 17-21.)

It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to incorporate the instantly claimed monomer into the

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antimicrobial contact lens of Sakuma since the monomer is a reverse amide analog of the monomer taught in Nochumson, which is a well known cross-linker, and Vanderlaan taught that soft contact lenses are a cross-linked polymeric system. Because the instant monomer is a reverse amide analog of the monomer of Nochumson it would reasonably be expected to have a similar function. When chemical compounds have “very close” structural similarities and similar utilities, without more, a *prima facie* case of obviousness may be made. *In re Wilder*, 563 F.2d. 457 (CCPA 1957). Stated alternatively, obviousness may be based solely upon structural similarity. See *In re Duel*, 51 F.3d 1552, 1559 (Fed. Cir. 1995). The necessary motivation to make the claimed compound, and thus the *prima facie* case of obviousness, arises from the reasonable expectation that compounds similar in structure will have similar properties. *In re Gyurik*, 596 F.2d 1012, 1018 (CCPA 1979).

It would have also been obvious to incorporate the senofilcon A of Vanderlaan into the antimicrobial contact lens of Sakuma, since the artisan would be motivated to provide an antimicrobial contact lens that has high oxygen permeability, sufficient elasticity and is comfortable to the contact lens wearer.

Also, the adjustment of particular conventional working conditions of the contact lens composition e.g. the amount of monomer and silver, is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Obvious-type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-10, 12-15, and 28-29 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 8-13, 15-27 and 42-44 of copending Application No. 10/703,777, claims 1-4 and 8-35 of copending Application No. 10/715,745, and claims 1-21, 28, 40, 41 and 43 of copending Application No. 10/715,903.

Although the conflicting claims are not identical, they are not patentably distinct from each other because each application claims a contact lens comprising silver and senofilcon A. The ‘777 application claims the instant elected monomer and the reverse amide analog, the analog being prima facie obvious as discussed above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter E. Webb whose telephone number is (571) 270-3287. The examiner can normally be reached on 8:00am-4:00pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Walter E. Webb
Patent Examiner
AU 1612

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/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612